New LCA Theses

Assessing the Impacts of Genetically Modified Microorganisms

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Abstract

The progression towards greater industrial sustainability involves the analysis of biotechnology as a means of achieving clean or cleaner products and processes. Because living systems manage their chemistry more efficiently than man-made factories, and their wastes tend to be recyclable and biodegradable, they can be expected to be more environmentally clean. Industry has begun to use enzymes instead of traditional catalysts in many industrial production processes.

The future holds obstacles as well as opportunities for biotechnological applications. A greater ability to manipulate biological materials and processes will have significant impact on manufacturing industries. A growing proportion of biotechnology-derived processes and products is based on the use of genetically modified microorganisms. This extends the analysis from the aspect of cleanliness to the aspect of safety.

Keywords: Biochemical engineering; biotechnology; genetically modified microorganisms; human health; impacts of biotechnology-derived processes and products; sustainability

1 Introduction

Biotechnology could play an important role in reducing the relative consumption of energy and raw materials, in recycling and the elimination of wastes. The move towards industrial sustainability will affect all stages of a product's or process' life cycle. To date, the best available tool to measure the cleanliness in a scientifically rigorous way is life-cycle assessment (LCA). LCA has already been performed by the biotechnological industry showing economic and environmental benefits [1].

The risk assessment of microorganisms used in biotechnology is an important prerequisite for introducing new production strains. Risks in respect to human health may be due to pathogenicity, allergenicity or the production of toxic metabolites. Pathogenic microorganisms may enter the human body and initiate an infection, depending on their transmissibility, infectivity and virulence [2,3]. We have investigated the possibilities of LCA to assess the safety of microorganisms used in industrial biotechnology.

2 Materials and Methods

LCA was applied on the pilot-plant fermentation of a biopharmaceutical. For the purpose of this study, the goal of LCA was defined to eliminate, reduce and manage the risks associated with the use of genetically modified microorganisms. All stages from raw material acquisition, fermentation and downstream processing, to waste management were considered under scope. The analysis of the biotechnological production system and its boundaries took advantage of the modular structure of fermentation processes [4].

Standard operation procedures (SOPs) for industrial manufacture were used as the basis for a life cycle inventory (LCI). Following LCA methodology, all inputs to the system and outputs to the work area and the environment were determined. Inputs and outputs were defined by the microorganism involved, actual concentrations and volumes. Data from SOPs were aggregated for life cycle assessment and analysed using the IDEA software [5].

3 Results

We tried to integrate the concept of risk assessment of microorganisms into the impact assessment of LCA in the following way: According to their hazardous characteristics, microorganisms, and genetically modified microorganims in particular, were assigned to more or less homogeneous impact categories, called risk classes (\rightarrow *Table 1*). The classification of microorganisms was qualitative and did not take into account the actual concentrations and volumes [3].

The probability of infection also depends on the amount and concentration of viable agents to which a person is exposed. LCA offered the opportunity for quantitative risk assessment taking into account volumes and concentrations.

Table 1: Risk classes of microorganisms based on the classification by the European Federation of Biotechnology (EFB)

- Microorganisms that have never been identified as causative agents of disease in man and that offer no threat to the environment.
- Microorganisms that may cause disease in man and which might, therefore, offer a hazard to laboratory workers. They are unlikely to spread in the environment. Prophylactics are available and treatment is effective.
- 3 Microorganisms that offer a severe threat to the health of laboratory workers, but a comparatively small risk to the population at large. Prophylactics are available and treatment is effective.
- 4 Microorganisms that cause severe illness in man and offer a serious hazard to laboratory workers and to people at large. In general, effective prophylactics are not available and no effective treatment is known.
- E Microorganisms that offer a more severe threat to the environment than to man. They may be responsible for heavy economic losses. This group includes several classes, Ep1, Ep2, Ep3 to accommodate plant pathogens.

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This approach requires quantitative factors for hazardous characteristics of individual microorganisms. Hazardous characteristics such as pathogenicity, allergenicity and toxicity were difficult to ascertain. However, some data on the number of organisms required to initiate infection (i.e. the infectious dose), could be obtained from the literature [2].

Quantitative risk assessment is valuable in particular with regard to aerosol transmittable microorganisms. If you know how many infectious doses will be handled at once and you know the air volume and ventilation rate of the room, you can calculate a maximum foreseeable exposure index. By extrapolation, it can be determined if that incident could result in an inhaled amount to produce infection.

Taking into account the risk class of the microorganism and its individual hazardous characteristics, the valuation of risks is the basis for risk management. This includes containment measures designed to prevent or at least minimise releases to the work area and the environment. Dependent on the microorganism, additional personal protection can be achieved via a vaccination.

4 Discussion

Apart from a "less is best" approach aiming at the reduction of volumes and concentrations, improvement can be accomplished by eliminating hazardous microorganisms from the production process. Containment measures for high risk microorganisms are particularly costly in terms of equipment, energy input and the use of hazardous chemicals. When hazardous microorganisms are replaced, certain containment measures may no longer be necessary to maintain adequate protection.

By recombinant cloning, genes of interest can by introduced into a stable, well known production organism. Concomitantly, the yield of the required product, e.g. an enzyme or pharmaceutical, can be increased. Results from this study support the notion that the use of genetically modified microorganisms provides environmental and economic benefits, and can improve the safety of the production process.

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5 References

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Book Reviews

Life Cycle Design for SMEs

Life Cycle Design, A Manual for Small and Medium-Sized Enterprises

Editors:

Behrendt, S., Jasch, C., Peneda. M.C., van Weenen, H.

Publisher: Springer Verlag, 1997; 44 Abb., 16 Tab., XV, 191 pages, 705 g Hardcover;

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The many thousands of small and medium-sized enterprises in the European Union are extremely important both economically and socially, because they account for more than 99% of all enterprises and for 65% of all employment and turnover. Environmental management systems and tools may be rather complicated and require well-educated manpower. Therefore, until now only relatively few SMEs have been able to adopt such systems, but both national and international organisations try to help promoting the message and guide the SMEs in a sustainable direction.

One such contribution is this manual for life cycle design which has been developed by a European research team with members from Germany, the Netherlands, Austria and Portugal. The manual is a result of an EU project which ran from April 1995 to April 1996. It is intended to serve as a source of information and ideas for environmental product development and for assisting SMEs in incorporating environmental criteria. It provides guidance at various levels of involvement and for different stages of product development. Further advantages by life cycle design are the potential cost saving and improved productivity due to a better developmental structure.

The book contains a lot of valuable background information about environmental management, legislation, standards and the product development process. The information, however, is related most to German-speaking countries. In addition, the book contains seven actual case examples of products improved by the life cycle design of different companies.

The core of the book is the actual manual with framework and tools showing how life cycle design can be realised. The fundament is checklists, with

criteria and A-B-C rating schemes, for each of the following 13 – ecological – principles:

- 1. Achieving environmental efficiency/optimal function
- 2. Saving resources
- 3. Use of renewable and sufficiently available resources
- 4. Increasing product durability
- 5. Design for product reuse
- 6. Design for material recycling
- 7. Design for disassembly
- B. Minimising harmful substances
- 9. Environmental friendly production
- 10. Minimising environmental impact of products in use
- 11. Using environmentally friendly packaging
- 12. Environmentally friendly disposal of non-recyclable materials
- 13. Implementing environmentally friendly logistics

The tool is simplified and should be useful for most SMEs, but it still requires more practical experience before a final evaluation of its usefulness is appropriate.

The book is highly recommendable, although some information is now somewhat outdated; for instance, the information about standards and web addresses. There are too many spelling errors of chemical names, and Figure 4.2 on page 38 is not understandable without an explanation.

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